Frederick L. Cottrell, III
302-651-7509
Cottrell@rlf.com

August 1, 2018

BY CM/ECF AND HAND DELIVERY
The Honorable Christopher J. Burke
United States District Court for the District of Delaware
844 North King Street
Wilmington, DE 19801

Re: *Collegium Pharm., Inc. v. Teva Pharms. USA, Inc.*, C.A. No. 18-300-LPS-CJB

Dear Judge Burke:

Per the Court's July 25, 2018, Oral Order, Plaintiff Collegium Pharmaceutical, Inc. ("Collegium") and Defendant Teva Pharmaceuticals USA, Inc. ("Teva") jointly submit this letter concerning the issue of narrowing the asserted claims and prior art.

Collegium's Position

The number of asserted claims and prior-art arguments[1] should be focused once before *Markman* briefing, on February 15, 2019, and again on October 4, 2019, the deadline for submitting final contentions. There are 229 claims in the 11 patents-in-suit. After its initial review of Teva's ANDA, Collegium's complaint cut down by 100 the number of asserted claims to 129, which it currently believes are infringed by Teva's ANDA Products. As requested by the Court, Collegium proposes that it further cut down the number of asserted claims to 75 (in conjunction with Teva's prior-art arguments being reduced to 120) by February 15, 2019,[2] and further down to 40 (in conjunction with Teva's prior-art arguments being reduced to 70) on October 4, 2019.[3] In addition, Collegium expects that the parties will then further narrow the case as expert discovery is completed and the parties meet and confer in assembling the final pretrial order so that a smaller number of claims and prior art arguments will remain for trial.

[1] Collegium requests that the Court define "prior art argument" (as it has done previously) to mean an argument that: (i) a single reference anticipates a claim; or (ii) a single reference renders a claim obvious; or (iii) a combination of references renders a claim obvious. Additionally, prior-art arguments shall be counted on a per-claim basis. Finally, a prior-art argument shall consist of those references that Defendant utilizes to show the existence of claim limitation(s) in the prior art. *See* C.A. No. 17-871-LPS-CJB, D.I. 68 at p. 1 n. 1.

[2] Based on the parties' agreed-upon schedule, Teva's Initial Invalidity Contentions are due December 3, 2018. The February 15, 2019 proposed first cut-down date, which is one week before opening claim construction briefs are due, affords Collegium enough time to review and analyze those initial contentions and choose a narrowing set of asserted claims.

[3] This date comports with the Court's prior orders narrowing cases, referenced in the July 25, 2018 Oral Order. In particular, the second cut-down dates in C.A. Nos. 17-871, 17-600, and 16-380, and the only cut-down date in C.A. No. 15-980 were all around the time of the deadline for plaintiff(s)'s final infringement contentions.

There is no basis for a cut-down immediately. First, Collegium has already reduced the number of asserted claims by 100 after its initial review of Teva's ANDA. Second, Teva knew the scope of the case it created when it certified against 12 Orange Book-listed patents covering Xtampza® ER, and provided the factual and legal basis for its assertion that **all** 259 of those claims were either invalid and/or not infringed. Much, if not all, of Teva's contention work is done, so there is no unfair prejudice to Teva, or Teva's counsel, to simply chart what it otherwise has already reduced to writing. Third, Teva's own statements undermine the case for a cut-down. In arguing for an earlier trial date, Teva went on record in stating that contrary to there being 11 asserted patents, this case is not that complicated. *See* July 23, 2018 Tr. at 10:5-15. Simply put, if Your Honor takes Teva at its word, then, given the so-called straightforward nature of this case, there is no need for any narrowing of asserted claims at this time. Finally, and perhaps most importantly, a cut-down now, and at the level proposed by Teva, would be premature and prejudicial to Collegium. None of the Court's prior orders narrowing cases, referenced in the July 25, 2018 Oral Order, included as many patents-in-suit as there are here. And none mandated a cut-down at this early stage. All of those orders implemented a first (and sometimes only) cut-down after at least initial contentions had been exchanged and some written discovery responses served. Collegium currently has insufficient information to determine which claims are best suited for trial. As this Court is well aware, the ANDA is the starting point in terms of the document production associated with Hatch-Waxman patent cases. Also relevant to the parties' positions concerning the scope of the claims and prior art are: Teva's work in formulating its ANDA products, lab notebooks, meeting minutes, testing results and analyses, formulators' testimony or statements in e-mails and any written record at attempts to design around. Equally as important are Teva's responses to contention interrogatories concerning the issue of, e.g., infringement.[4] Without this information, Collegium can only speculate as to the claims that most clearly present the best issues for trial.

Teva's proposal does not comport with Your Honor's prior orders narrowing down these types of cases. Teva's proposed first cut-down date, October 8, 2018, is two months before Teva is due to serve its initial invalidity contentions. Teva's basis for the October 8 first cut-down date is that Collegium would have had 10 months to review Teva's ANDA, but it ignores the other relevant discovery referenced above that is necessary for Collegium to consider in making a first—in fact, second—significant cut-down. The number of asserted claims contemplated by Teva's second cut-down, 22, ignores the fact that this is an eleven-patent case. Teva's 22 asserted claims proposal mirrors the number of asserted claims in some of the Court's prior orders, but does not take into account that most of those orders have one-third the amount of patents-in-suit, i.e., three or four, and no more than seven. Assertion of two claims per patent on average is an extreme limitation and unfair. Teva talks about the "extremely burdensome" task of preparing initial contentions and the "countless claim terms in dispute should Collegium continue asserting 129 claims through the *Markman* process." But those arguments ring hollow because they are without any factual basis and entirely speculative. Teva's reliance on the Federal Circuit's Advisory Committees Model Order is of no moment. The Federal Circuit explicitly stated that it

[4] It bears noting that in its pre-suit Paragraph IV certification notice letter, Teva did not raise non-infringement arguments with respect to a vast majority of the asserted claims; it raised no non-infringement arguments with respect to four of the patents-in-suit. Thus, Teva can certainly help its, and the Court's, efforts at narrowing the case by stipulating to infringement of those claims for which it did not raise a non-infringement argument.

"has not sponsored or endorsed the order[]." *See* http://www.cafc.uscourts.gov/sites/default/files/model_orders.pdf. Finally, Teva's proposal to narrow its invalidity case to 82 and 28 prior art references, respectively, rather than prior-art arguments as Collegium proposes, is illusory. Even with 28 references, Teva can come up with dozens of prior-art combinations to assert against the asserted claims, rendering any "narrowing" down of the case meaningless.

Teva's Position

Permitting Collegium to continue asserting 129 claims through the contentions and *Markman* phases would be extremely burdensome on both the parties and the Court. To wit, Collegium will need to prepare initial infringement contentions while Teva will need to prepare initial invalidity contentions for 129 different claims. Similarly, the parties will need to brief, and the Court will need to construe, countless claim terms in dispute. Based on such efficiency concerns, the Federal Circuit has held that district courts may limit the number of patent claims asserted by a plaintiff so long as the plaintiff is allowed to seek leave to add additional claims upon a showing of good cause. *See In re Katz Interactive Call Processing Patent Litig.*, 639 F.3d 1303, 1312 (Fed. Cir. 2011). Consistent with the holding in *Katz*, this Court has frequently entered scheduling orders that include an early reduction of asserted claims. *See, e.g., Forest Labs. Inc., et al. v. Teva Pharms., USA, Inc., et al.*, C.A. No. 14-121-LPS, D.I. 61 at 10-12 (D. Del. November 20, 2014) (Ex. 1); *Robert Bosch LLC v. Alberee Products, Inc.*, C.A. No. 12-574-LPS, D.I. 67 at 13 (D. Del. September 10, 2014) (Ex. 2); *Reefedge Networks, LLC v. Aruba Networks, Inc. et al.*, C.A. No. 12-1042-LPS, D.I. 48 at 5-6 (D. Del. September 6, 2013) (Ex. 3).

Teva respectfully requests that the Court require Collegium to narrow the number of asserted claims in two-stages, a procedure this Court has repeatedly used. *Integra LifeSciences Corp., et al. v. HyperBranch Medical Technology, Inc.*, C.A. No. 15-819 (LPS) (CJB) (D. Del. September 2, 2016 and October 2, 2017 Oral Orders) (Exs. 4a and 4b) (requiring plaintiff to reduce the asserted claims in two stages); *see also Tessera, Inc., et al. v. Broadcom Corp.*, C.A. No. 16-380-LPS-CJB (D. Del. October 17, 2016 Oral Order) (Ex. 5) (same); *Thermo Fisher Scientific Inc., et al., v. Agilent Technologies, Inc.*, C.A. No. 17-600-LPS-CJB (D. Del. February 5, 2018 Oral Order) (Ex. 6) (same). Specifically, Teva proposes the following:

Stage 1: On October 8, 2018, Collegium must reduce the number of asserted claims to no more than 65 (with a corresponding reduction to 82 prior art references by Teva[5]).

Stage 2: On August 6, 2019, Collegium must further reduce the claims remaining after the Stage 1 reduction to no more than 22 (with a corresponding reduction to 28 prior art references).

Under Teva's proposal, Collegium would make its initial election of 65 asserted claims on October 8, 2018 – its deadline for serving initial infringement contentions. *See* Joint [Proposed] Scheduling Order, Dkt. No. 20, at p. 4, ¶ 7 c. Because this date is ten months *after* Collegium first received access to Teva's ANDA and nearly two months *after* receiving Teva's core technical documents, Collegium will have sufficient time (and information) to reduce the number of asserted claims from 129 to 65.

Requiring Collegium to narrow the number of asserted claims at the time it serves its initial infringement contentions will increase efficiencies for both parties, as the burdens of charting

[5] Teva additionally requests that its proposed limitations regarding prior art references should not limit Teva's ability to provide evidence of background knowledge in the art.

infringement and invalidity contentions for 65 claims is much less onerous than for 129 claims. *See, e.g., Network Protection Scis. LLC v. Juniper Networks, Inc.*, 3-12-cv-01106, Dkt. No. 197 at *3 (N.D. Cal. May 9, 2013) (Ex. 7) (noting the "unreasonable burden" of requiring the defendant to "conduct[] a prior art search for more than fifty patent claims," where most claims will never actually be asserted); *see also Confluent Surgical, Inc. et al v. HyperBranch Medical Technology, Inc.*, C.A. No. 17-688-LPS-CJB (D. Del. Oct. 30, 2017 Oral Order) (Ex. 8).

Teva's October 8, 2018 initial election date is also more than two months before the parties exchange claim terms for construction (December 14, 2018). *See* Dkt. No. 20, at p. 9, ¶ 11. Narrowing the number of asserted claims will undoubtedly reduce the claim construction disputes. In fact, this Court has previously recognized the efficiency of significantly narrowing the asserted claims before *Markman* briefing begins. *See, e.g., Intellectual Ventures I LLC v. AT&T Mobility LLC*, C.A. No. 12-193-LPS, D.I. 85 (D. Del. Sept. 17, 2013 Oral Order) (Ex. 9) (narrowing more than 400 claims asserted from 16 patents with 14 unique specifications to no more than 5 asserted claims per unique patent specification before the *Markman* hearing); *Softview, LLC v. Apple, Inc. & AT&T Mobility, LLC*, C.A. No. 10-389-LPS, D.I. 105 at 35, ll. 2-14 (D. Del. Sept 20, 2011) (Ex. 10) (same).

In contrast, Collegium has not articulated any meaningful reason for why it cannot make its initial election by October 8, 2018. Instead, Collegium alleges that "[m]uch, if not all, of Teva's contention work is done, so there is no real prejudice to Teva, or Teva's counsel, to simply chart what it otherwise has already reduced to writing." But, as Collegium's counsel correctly conceded at the Case Management Conference, Teva is not constrained by the factual and legal bases provided upon certification.[6] Teva can, and intends to, include other prior art/arguments in its invalidity contentions. Collegium also alleges that Teva's statements regarding the lack of complexity of the case undermine the need for a reduction. But, even if a case is not "complicated," it would still be extremely burdensome to chart 129 claims.

Teva also requests that Collegium be required to further reduce the number of asserted claims to no more than 22 on August 6, 2019. Teva chose this date for the second reduction in order to provide Collegium with sufficient time after the *Markman* ruling to make this election. Specifically, the Court indicated at the Case Management Conference that its "goal" was to issue its *Markman* ruling within 60 days of the April 5, 2019 *Markman* Hearing – *i.e.*, by June 5, 2019 – giving Collegium two months to consider that ruling prior to further narrowing the case. *See* Hearing Tr., at 32, ll. 4-6. Further, August 6, 2019 date is a month and half before opening expert reports are due (on September 20, 2019) and thus would allow the parties to efficiently focus their expert reports on a much more limited set of asserted claims. *See* Dkt. No. 20, at p. 6, ¶ 7j.i.

In short, requiring Collegium to narrow its case in the two-stage manner proposed by Teva is reasonable and would be efficient for both the parties and the Court. Accordingly, Teva respectfully requests that the Court adopt Teva's proposal.

[6] *See* July 23, 2018 Case Management Conference Hearing Tr., at 25, ll. 4-10.

Respectfully,

/s/ Frederick L. Cottrell

Frederick L. Cottrell, III (#2555)

cc: Counsel of Record